REMARKS

Claims 3 and 5-10 are pending; Claims 1-2, 4 have been cancelled.

In the Office Action mailed January 7, 2010, claims 3 and 5-9 have been rejected as allegedly anticipated under 35 U.S.C. § 102(b) over U.S. Patent No. 5,698,195 to Le et al. (*"Le"*). Claims 3 and 5-9 have been rejected as allegedly indefinite under 35 U.S.C. § 112, second paragraph. Claims 3 and 5-9 have been rejected as allegedly lacking written description under 35 U.S.C. § 112, first paragraph. Claims 3 and 5-9 have been rejected as allegedly lacking enablement under 35 U.S.C. § 112, first paragraph.

By this Amendment, Applicant amended claim 1. Applicant respectfully requests reconsideration and allowance of the pending claims in view of the remarks set forth below.

I. ANTICIPATION REJECTION OVER *LE*

All pending claims have been rejected as allegedly anticipated by *Le*. All pending claims recite a "homeopathically potentized" form of an antibody to inflammatory cytokines. As now amended, all claims recite "homeopathically potentized form . . . wherein said homeopathically potentized form of antibody is prepared by homeopathic methodology that includes multiple consecutive dilutions." In the Office Action, the Examiner asserted "antibody is inherently homeopathically potentized form." Office Action, at page 8. Thus, the Examiner apparently asserts that *Le* discloses a "homeopathically potentized form" recited in the rejected claims because certain dilutions of *Le* could result in "homeopathic potentiation or activation."

To anticipate a claim, a reference must disclose either explicitly or inherently, each element of the claim "as set forth in the claim." MPEP §2131, *citing*, *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). It is undisputed that *Le* does not disclose anything related to homeopathy or homeopathic technology, nor does it provide any disclosure of multiple consecutive dilutions. Specifically, *Le* does not disclose, either explicitly or inherently, preparation of any form of antibody "by homeopathic methodology that includes **multiple consecutive dilutions**." The anticipation rejection cannot stand if the reference does not disclose all claim elements. MPEP §2131.

Further, the Examiner did not set forth a *prima facie* case of inherent anticipation even with respect to the term "homeopathically potentized." A finding of inherent anticipation requires a showing that, while not disclosed explicitly, the prior art composition possesses the properties of the claimed composition. MPEP §2112. *See also Schrieber*, 128 F.3d at 1478. To make a *prima facie* case of inherent anticipation, the Examiner must come forth with a scientific rationale or objective evidence tending to show inherency. *In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993). Only if the Examiner successfully sets forth the requisite evidence or rationale, then and only then the burden shifts to the patent applicant to come forward with an evidentiary showing to rebut the *prima facie* case of inherent anticipation. *Rijckaert*, 9 F.3d at 1534.

The Examiner did not present evidence or scientific rationale that any process of *Le* would result in "homeopathically potentized" antibodies beyond an unsupported assertion that any dilution would lead to homeopathic potentiation. Such assertion is manifestly insufficient to satisfy the U.S. PTO's burden of setting forth a *prima facie* case of inherent anticipation under the law. There is simply no reason to believe that such simple dilution would result in homeopathic potentization. The essence of the Examiner's position appears to be that any solution containing a starting antibody is anticipated by Le, while a solution containing no detectable antibody is simply a buffer. *See* Office Action, at pages 8-9. This position simply ignores the substance of the present invention, namely, the presence of "homeopathically potentized" form of an antibody, which has independent existence and which is claimed in the present application. The Examiner plainly equates the pharmaceutically active, "homeopathically potentized" form of antibody with a placebo. The Examiner's position ignores evidence in the file wrapper. For example, the data set forth in the Example 2 of the specification, show that the properties of the claimed "homeopathically activated" form of antibodies are different from the placebo control. Example 2 was done in the rat model, which cannot exhibit a placebo effect.

If the Examiner will continue to make this assertion going forward in the present prosecution, the Examiner is respectfully requested to set forth specific portions of *Le* which the Examiner considers anticipatory and provide some further elaboration. If and only if such identification of relevant portion of *Le* and elaboration of specific reasoning

were to be sufficient to meet the burden imposed upon the U.S. PTO under the law, the Applicant would be obligated to come forth with an evidentiary showing that *Le* does not set forth "homeopathically potentized form." At a minimum, such elaboration and identification would enable the Applicant to consider which evidentiary showing would be appropriate.

Again, and apart from the inherency argument, it is a simple fact that Le does not teach the use of homeopathic methodology and multiple consecutive dilution, which are explicit claim limitation of amended claim 3.

Withdrawal of the anticipation rejection is respectfully requested.

II. REJECTIONS UNDER 35 U.S.C. 112

The Examiner rejected all pending claims as allegedly indefinite under 35 U.S.C. §112, second paragraph, asserting that "the term 'homeopathically activated form" is ambiguous and confusing because the metes and bounds of the term is not clear." Office Action, at page 3.

"In reviewing a claim for compliance with 35 U.S.C. 112, second paragraph, the examiner must consider the claim as a whole to determine whether the claim apprises one of ordinary skill in the art of its scope and, therefore, serves the notice function required by 35 U.S.C. 112, second paragraph, by providing clear warning to others as to what constitutes infringement of the patent [*emphasis added*]." MPEP 2173. Applicant respectfully directs the Examiner to the *Epstein Declaration*, including Exhibit A, and the *Nikolayev Declaration*, which were filed on October 29, 2009. Both declarants unequivocally stated that the term "homeopathic potentization" has a well-defined meaning in the homeopathic art. The *Epstein Declaration* and the *Nikolayev Declaration* are amply supported by the overall state of the homeopathic art, including the excerpt from the German Homeopathic Pharmacopeia submitted in evidence with Amendment filed on October 29, 2009. The Examiner made reference to an article by Goldacre (Lancet, 2007), which alleges that "homeopathy produced no statistically significant benefit over placebo." *See* Office Action, at page 4. However, the evidence presented by the Examiner is not relevant to the indefiniteness inquiry. First, the claimed invention

relates to "homeopathically potentized form" of **antibodies**. Dr. Oleg Epstein, the inventor of the present application is the originator of the concept of homeopathic methodology to **antibodies**. None of the studies reviewed or discussed in the Lancet article describe antibodies. Second, as set forth above, the evidence in the file wrapper establishes that the claimed "homeopathically potentized" form of antibodies has activity. In the absence of any evidence to the contrary, it is submitted that the Examiner should give this evidence the weight it deserves. Third, the claims as amended, now recite "homeopathically potentized form of . . . antibody, wherein said homeopathically potentized form of antibody is prepared by homeopathic methodology that includes multiple consecutive dilutions." The added claim language makes clear the genesis of the claimed "homeopathically potentized form" of antibody. Therefore, the evidence now in the file wrapper clearly establishes that rejected claims are clear to one of ordinary skill in the art. Withdrawal of the indefiniteness rejection is respectfully requested.

The pending claims also have been rejected as allegedly lacking written description under 35 U.S.C. §112, first paragraph.

As amended, claim 3 now recites:

> 3. (Currently Amended) A medicament effective in correcting a pathologic immune reaction, said medicament comprising a homeopathically potentized form of at least one monoclonal polyclonal or natural antibody to a recombinant human or heterologous tumor necrosis factor alpha (TNF-α), wherein said homeopathically potentized form of antibody is prepared by homeopathic methodology that includes multiple consecutive dilutions.

According to the Examiner:

> Claims encompass treatment with an antibody which is a "homeopathically potentized form." However, the essential feature of the invention is not clear because the structure which makes an antibody homeopathically potentized is not disclosed. Using the disclosure one of skill in the art cannot envision the homeopathically potentized molecules of the claimed antibody molecules for the treatment.

See Office Action, at page 4.

Before responding to specific basis for the rejection, Applicants again note that *haec verbis* disclosure is not a pre-requisite for complying with the written description requirement. *See* MPEP § 2163. I. B. The description may be express, implicit, or inherent. *Id.* The key to evaluating compliance with the written description requirement is a determination whether the applicant had possession of the claimed invention based on the content of the application as a whole. *See* MPEP § 2163. II. The outcome of the evaluation depends on whether "the description clearly allows persons of ordinary skill in the art to recognize that he or she invented what is claimed." *See* MPEP § 2163.01, *citing In re Gostelli*, 872 F.2d 1008, 1012 (Fed. Cir. 1989).

The specification describes: a) preparation of "potentiated" antibodies to TNF-α by homeopathic technology (*e.g.*, at page 2, 3rd and 4th paragraph), b) administration of the activated or potentiated form of the antibody to TNF-α to patients (*e.g.*, Examples 3 and 4), and c) biological effects of such administration in an animal model (*e.g.*, Examples 1 and 2). The term "potentised" or "activated" have a well defined meaning in the homeopathic art. Attached with the *Epstein Declaration* was the Exhibit A which is an excerpt from a published English language translation of German Homoeopathic Pharmacopoeia (GHP) (1991). GHP is a voluminous, standard reference text on homeopathy. The attached Exhibit A includes the i) the title page, ii) the content page, iii) a page from the section entitled "Formulations and Presentations," and iv) a portion of the monograph entitled "Manufacture." In the section of the attached Exhibit A entitled Formulations and Presentations, the GHP teaches:

> Liquid formulations are mother tinctures and solutions, as well as liquid dilutions of these; solid formulations are triturations of these (triturations). Different concentrations of these formulations (degrees of dilution) are obtained by *potentization*.
>
> *Potentization* in this context is the dilution by stages of solid or liquid formulations by the stated Method.
>
> The letter x [D in German usage] is used to designate dilutions made in a ratio of 1:10, the letter c [C in German usage] dilutions made in a ratio of 1:100.
>
> A figure added to the designatory letters 'x' and 'c' refers to the number of dilution stages [*emphasis in the original*].

In the section entitled "Manufacture," the GHP describes standard homeopathic preparation technologies for various known homeopathic preparations. For each described method, the GHP describes the necessary potentization methodology. It is clear from the Exhibit A, together with the specification as a whole (including section identified with specificity) and as supported by the *Epstein Declaration* and *Nikolayev Declaration*, that the meaning of the term "homeopathic potentization" is well defined to one skilled in the art at the time of filing of the present application.

The Examiner's assertion may be summed up as an objection to lack of disclosure of the specific structure of "homeopathically potentized form" of antibody. However, possession of the invention may be shown in many ways. *See* MPEP § 2163. II. As set forth, the specification describes how to make the "homeopathically potentized form," including the starting material, and describes its activity. It is respectfully submitted that such description is sufficient to establish possession. Further, claim 3, as amended, now specifically recites that "homeopathically potentized form" of an antibody is prepared via multiple consecutive dilution. Applicants respectfully submit that amended claim 1 and all dependent claims are fully supported in the application as filed. Withdrawal of the rejection is respectfully requested.

The Examiner also rejected all pending claims for alleged lack of enablement. The bases for this rejection are unclear to the undersigned. As set forth above, Examiner's view that the claimed "homeopathically potentized form" of antibodies is equal to placebo is not in accordance with evidence in the file wrapper. However, even assuming, *arguendo*, that it is, the specification, together with state of the art evidence present in the file wrapper, clearly teaches how to use and how to make the claimed form of antibodies. The claims are directed to a potentized form of antibody prepared by multiple consecutive dilutions. Thus, a skilled artisan would make multiple consecutive dilutions until the antibody is potentized and show activity in an accepted model of pharmacological activity.

In view of the foregoing, the Applicants submit that all claims are in condition for allowance. Accordingly, both reconsideration of this application and its swift passage to

issuance are earnestly solicited. In the event that there are any fees due and owing in connection with this matter, please charge the same to our Deposit Account No. 50-4711.

Respectfully submitted,

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